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EXAMINER	
HOWARD, ZACHARY C	

ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,588	BJURSELL ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 9* is/are pending in the application.

4a) Of the above claim(s) *3,5,6,8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4* is/are rejected.

7)☒ Claim(s) *1,2 and 4* is/are objected to.

8)☒ Claim(s) *1-6,8 and 9* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/07;5/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: PTO-Notice to Comply with Sequence Disclosure Requirements; PTO-90C Sequence Compliance Letter.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-6, 8 and 9 are pending in the instant application.

Election/Restrictions

Applicants' election without traverse of Group I, claims 1, 2 and 4, in the reply filed on 7/27/09 is acknowledged.

Claims 3, 5, 6, 8 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 7/27/09.

Claims 1, 2 and 4 are under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Specifically, page 14, lines 15 and 16, of the specification shows four nucleic acid sequences. However, the instant specification does not include a Sequence Listing includes said sequences. Applicants must provide:

(a) an initial computer readable form (CRF) copy of the Sequence Listing;

(b) an initial paper copy of a Sequence Listing, as well as an amendment directing its entry into the specification;

(c) a statement that the content of the paper and computer readable copies are the same, and where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d); and

(d) an amendment to the specification such that each of the four sequences on page 14 is accompanied by a sequence identifier.

Applicants must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Please see attached PTO-90C and PTO-Notice to Comply.

Specification

The disclosure is objected to because of the following informalities:

(1) The title of the invention ("METHOD") is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

(2) The disclosure is objected to because the Brief Description of Figure 4 (pg 12) does not refer to Figure 4A, 4B and 4C, and the Brief Description of Figure 5 (pg 12) does not refer to Figure 5A, 5B and 5C. See 37 CFR § 1.74, which states “there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter)” and MPEP 601.01(g) which states “if the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected". It is noted that each figure refers to "Panel A", "Panel B" and "Panel C"; however, for clarity these should be amended to refer to "Figure 4A", "Figure 4B", "Figure 4C", "Figure 5A", "Figure 5B" and "Figure 5C".

Appropriate correction is required.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Applicants submitted a declaration on 4/16/08. However, this declaration is defective because non-initialed and non-dated alterations have been made to the declaration. See 37 CFR 1.52(c). Specifically, the addresses of the Applicants Karl Bjursell and Jeanette Nilsson have each been altered without including a corresponding set of initials and date. The execution of the declaration by said Applicants is not sufficient to meet this requirement. See MPEP 605.04(a): "Any changes made in ink in the application or oath prior to signing should be initialed and dated by the applicants prior to execution of the oath or declaration. The Office will not consider whether noninitialed and/or nondated alterations were made before or after signing of the oath or declaration but will require a new oath or declaration."

It is noted that this objection can be overcome by filing a corrected declaration or by filing an application data sheet (ADS) including the addresses of the Applicants.

Claim Objections

Claims 1, 2 and 4 are objected to because of the following informalities:

The acronym CEL should be accompanied by the full terminology ("carboxyl ester lipase") in each of independent claims 1, 2 and 4.

In claim 4, line 3, the term "modulator" should be plural.

In claim 4, line 4, the term "procedure" should be plural.

In claim 4, line 4, the term "compound" should be plural.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it is unclear whether or not the modulator recited in line 3 has already been tested for modulation of binding affinity of CEL to a receptor, or whether it will be tested for modulation of binding affinity as part of the claimed method. If the modulator has already been tested, clarity could be added by amending the claim to recite, for example, "...one or more putative modulators that modulate the binding affinity of CEL to a receptor as test compounds..." If the modulator will be tested for modulation of binding affinity as part of the claim, then the claimed method is incomplete because it does not recite a method step wherein a modulator of the binding affinity of CEL to a receptor is measured and identified.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is as follows. Independent claims 1 and 2 are directed to method of identifying a compound which comprises assaying the compound for its ability to modulate the binding affinity of CEL to a receptor. The intended use of claim 1 is to identify a compound "useful for prevention and treatment of atherosclerosis", and

the intended use of claim 2 is to identify a compound "useful for reducing the retention of atherogenic lipoproteins in atherogenesis". Independent claim 4 is directed to a method which comprises using one or more putative modulator of the binding affinity of CEL to a receptor as a test compound in one or more procedure to measure the ability of the test compound to reduce the retention of atherogenic lipoproteins, and selecting an active compound. The method of claim 4 has the intended use of providing "an agent for the reduction of the retention of atherogenic lipoproteins in atherogenesis" (said intended use is recited in both the preamble of the claim and in the method step directed to selection of an agent). While the recited intended uses bear no accorded patentable weight to distinguish the claimed methods over one from the prior art, enablement of the claimed method requires that the methods identify compounds that fulfill the recited intended uses. Thus, for the specification to enable the skilled artisan to use claim 1, the specification must enable the skilled artisan to practice the method of claim 1 such a compound is identified that is useful for prevention and treatment of atherosclerosis. Likewise, for the specification to enable the skilled artisan to use claim 2, the specification must enable the skilled artisan to practice the method of claim 1 such that a compound is identified that is useful for reducing the retention of atherogenic lipoproteins in atherogenesis. Likewise, for the specification to enable the skilled artisan to use claim 4, the specification must enable the skilled artisan to practice the method of claim 4 such that a compound is identified that for the reduction of the retention of atherogenic lipoproteins in atherogenesis.

The specification teaches that the term "CEL" recited in the claims is an abbreviation for "carboxylethyl lipase" also known as bile salt stimulated lipase (BSSL) or bile salt stimulated cholesterol esterase (¶ 8). The specification teaches that "CEL is involved in the digestion and absorption of dietary lipids" (¶ 8) but a "wider role for CEL in lipid metabolism is implicated by the presence of CEL mRNA and activity in human plasma and aortic tissue (Shamir et al. 1996)" (¶ 8).

The specification provides the following working examples in support of the claimed invention. Example 1 is titled "CEL Co-localizes with Macrophages in Human Atherosclerotic Lesion" and shows that CEL and the macrophage marker CD68 are

present in overlapping locations in sections of atherosclerotic carotid arteries from three individuals (¶ 82). Example 1 further reports that CEL mRNA and protein is detectable in both primary monocytes and in *in vitro* activated macrophages (primary monocytes PMA-treated to induce macrophage-like phenotype) (¶ 84). A time course of CEL expression shows that "there is no apparent up-regulation of CEL over this time when the monocytes are differentiated into macrophages"; this result was the same whether the cells were treated with PMA, LPS, IFN-γ or ox-LDL (¶ 85). Example 1 further reports CEL and apoB co-staining "in the same regions of the atherosclerotic carotid artery, and the "amount of CEL appeared to a certain extent correlated to the amount of apoB" in HDL/LDL fractions of serum from donors with high chylomicron content. (¶ 86). The specification also contains Examples 2-5; however, these are prophetic examples rather than working examples. Each Example describes how to test the affinity of CEL to proteoglycan (Example 2), scavenger receptors (Example 3), lipoprotein particles (Example 4) or lipoproteins (Example 5), and further indicates that the test compounds can be screened to identify modulators of binding.

The specification further advances the "response-to-retention hypothesis" which "suggests that subendothelial retention of atherogenic lipoproteins is the trigger for all of these processes [implicated in the early stages of atherosclerosis] which are in fact normal physiological responses to accumulation of lipids" (¶ 4) and "the affinity to which LDL bind to vascular proteoglycans is a determinant of subendothelial retention" (¶ 16). The specification further teaches "[t]he binding of CEL to vascular proteoglycans remains to be thoroughly investigated", underscoring that Example 2 is a prophetic example.

While the working examples show an association between CEL expression and atherosclerosis, they fail to provide any evidence of whether CEL is a cause or a symptom of the lesions. Furthermore, even assuming that CEL is a cause of the lesions, the specification fails to identify any specific receptor that promotes atherosclerosis through interaction with CEL. The claims require that the modulation of binding of CEL to a receptor is an indication of whether a compound is useful for prevention and treatment of atherosclerosis or reducing the retention of atherogenic lipoproteins in

atherogenesis. However, instead of enabling the skilled artisan to practice the claimed method by providing an interaction between CEL and a specific receptor that promotes atherosclerosis, the specification simply advances an vast and varied genus of "suitable receptors" including proteoglycans such as glycosaminoglycans, heparin, heparan sulphate, chondroitin-6-sulphate, chondroitin-4-sulphate, dermatan sulphate; scavenger receptors such as SR-A types I, II and III, MARCO, SR-BI, CD36, SR-C1, SR-D, Macrosialin/ CD86, SR-E, LOX-1 (lectin-like ox-LDL receptor), SR-F, SREC-1, SR-PSOX, FEEL-1, FEEL-2; AGE receptors such as RAGE, 80K-H, OST 48, Galectin-3 … LPL (lipoprotein lipase); apolipoproteins such as apo A-I, apo A-II, apo B-100, apo B-48, apo C-I, apo C-II, apo C-III, apo E; lipoproteins and lipoprotein particles such as the VLDLs (very low-density lipoproteins) VLDL1, VLDL2 and VLDL3, the IDLs (intermediate-density lipoproteins) IDL1, IDL2 and IDL3, LDLs (low density lipoproteins) LDL1, LDL2 and LDL3, the HDLs (high-density lipoproteins) preβ-HDL, α-HDL, HDL1, HDL2, and HDL3 ... as well as chylomicrons". While CEL may bind one or more of these compounds (e.g., the prior teaches binding of CEL to heparin), the specification fails to teach which, if any of these compounds, binds CEL as part of the atherogenic process, such that modulating the interaction would result in treatment of atherosclerosis and/or reducing the retention of atherogenic lipoproteins. The specification even fails to indicate what form of modulation (increasing or decreasing binding affinity) is required; the specification at ¶ 22 teaches indicates that compounds that increase or decrease the binding affinity of CEL to a receptor are encompassed by the claims. The specification merely invites the skilled artisan to engage in further experimentation to determine (1) whether or not CEL is actually a cause of atherosclerosis and (2) if so, the nature of any receptor (if any) that binds CEL such that the interaction is involved in the process.

Bengtsson-Ellmark et al (2004. Eur J Hum Genetics. 12: 627-632; reference C20 on the 5/22/09) teaches that "(CEL) is involved in the hydrolysis and absorption of dietary lipids, but is largely unknown to what extent CEL could be involved in determining the serum lipid Levels" (see Abstract). Bengtsson-Ellmark et al (2004) was published after the early date to which the instant application claims priority, thus

providing evidence that the skilled artisan could not predict what the role of CEL in atherogenesis was at the time of filing of the instant application.

Claim 4 additionally lacks enablement because the specification fails to teach "one or more procedure to measure the ability of the test compound to reduce the retention of atherogenic lipoproteins". No specific procedures of this type (either *in vitro* or *in vivo*) are referred to and it is not clear how such a procedure could be designed in absence of a specific molecule that CEL binds to as part of promotion of retention of atherogenic lipoproteins. As such, the specification does not provide sufficient guidance for the skilled artisan to conduct such procedures.

Due to the large quantity of experimentation necessary to determine if the claimed methods could be used to identify compounds for the intended uses recited in the claims, the lack of direction/guidance presented in the specification regarding same, lack of working examples and the teachings of the prior art and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed invention.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicants are claiming and what Applicants have possession of.

Possession of the claimed method requires a description of an interaction between CEL and "a receptor" such that said interaction is involved in atherosclerosis and retention of atherogenic lipids. The term "receptor" recited in the claims is not provided with a limiting definition in the specification and potentially encompasses any protein that binds CEL. The specification advances a vast and varied genus of "suitable

receptors" (described above) that included a diversity of protein structures proteins (e.g., glycoproteins and lipoproteins). While CEL may bind one or more of these compounds (e.g., the prior teaches binding of CEL to heparin), the specification fails to describe which, if any of these compounds, binds CEL as part of the atherogenic process, such that modulating the interaction would result in treatment of atherosclerosis and/or reducing the retention of atherogenic lipoproteins. Thus, the specification fails to provide possession of "a receptor" as recited in the claims, and the claimed method lacks written description.

Claim 4 additionally lacks written description because the specification fails to describe "one or more procedure to measure the ability of the test compound to reduce the retention of atherogenic lipoproteins". No specific procedures of this type (either *in vitro* or *in vivo*) are described and it is not clear how such a procedure could be designed in absence of a specific molecule that CEL binds to as part of promotion of retention of atherogenic lipoproteins. As such, the specification does not provide sufficient description for the skilled artisan to possess such procedures.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See pg 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (pg 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of receptors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai* Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGFs were found to

be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claims fail to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicants are reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see pg 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange et al, EP 0650620, published 3/1/95 (reference B1 on the 3/21/07 IDS).

The term "CEL" used in claim 1 is an abbreviation for "carboxylester lipase". This enzyme is also known as "pancreatic cholesterol esterase" or PCE. This is evidenced by Pfutzer et al (2002. Pancreas. 25(1): 101-106; cited herein solely to provide evidence that PCE and CEL are inherently the same), which refers to pancreatic cholesterol esterase by the acronym CEL (see Abstract).

The recitations of "useful for prevention and treatment of atherosclerosis" in the preamble of claim 1 and "useful for reducing the retention of atherogenic lipoproteins in atherogenesis" are each interpreted as an intended use and bear no accorded patentable weight to distinguish the claimed methods over one from the prior art. The recitation "useful for prevention and treatment of atherosclerosis" and "useful for reducing the retention of atherogenic lipoproteins in atherogenesis" have not been given patentable weight because each recitation occurs in the preamble of a claim. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process

steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). As such, claims 1 and 2 each encompass a method of identifying a compound which comprises assaying the compound for its ability to modulate the binding affinity of CEL to a receptor.

Lange et al teaches a "a mammalian pancreatic esterase receptor (PCE^R), preferably human PCE^R)" (col 3, lines 9-11). Lange et al further teach that "methods and reagents for isolating and characterizing agents capable of inhibiting or modulating the binding of PCE to PCE^R" (col 3, line 56 through col 4, line 1). Thus, Lange et al teach a method of identifying a compound (e.g., an agent) which comprises assaying the agent for its ability to modulate the binding affinity of PCE to a receptor (PCE^R). This teaching is encompassed by each of claims 1 and 2, and therefore Lange et al anticipates claims 1 and 2.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647